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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,146	02/01/2002	Roland Cherif Cheikh	0512-1009-1	1738

466 7590 03/13/2006

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EXAMINER	
VU, JAKE MINH	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,146	CHEIKH, ROLAND CHERIF	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-100* is/are pending in the application.

4a) Of the above claim(s) *91-94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-90 and 95-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 74-100 are pending in the instant application. Claims 91-94 are withdrawn from consideration.

Election/Restrictions

During a telephone conversation with Mr. Philip Dubois on 02/17/06 a provisional election was made with traverse to prosecute the invention of Group I, claim 74-90 and 95-100. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 91-94 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

Claim 79 recites the limitation "according to Claim 73". There is insufficient antecedent basis for this limitation in the claim, because Applicant had previously canceled claim 73.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-77, 80-87, 89, 90, 95-100 are rejected under 35 U.S.C. 102(b) as being anticipated by HUTCHINSON (US 5,366,734).

Applicant's claims are directed to a composition comprising of: at least 50% of an active agent, such as leuteinizing hormone-releasing hormone; and a biodegradable excipient, such as polylactide-glycolide, wherein the release profile of the active agent is continuous. The composition has a thin and elongated form with a diameter not exceeding 3mm and the copolymers having an intrinsic viscosity greater than 0.6 dl/g.

HUTCHINSON disclosed a composition for implants (col. 16, line 24) comprised of: at least 50% of an active agent (col. 9, line 1-25), such as leuteinizing hormone-releasing hormone (col. 2, line 67); and a biodegradable excipient, such as polylactide-glycolide (col. 1, line 64), wherein the release profile of the active agent is continuous (abstract and col. 9, line 39). The composition has a thin and elongated form with a diameter not exceeding 3mm (col. 17, line 53-54) or in the form of spheres/pellets (col. 8, line 55-57); and the copolymers having an intrinsic viscosity greater than 0.6 dl/g (col. 9, line 1-25).

Note, the limitations of "not forming a matrix", "duration of release is substantially greater in vivo than in a physiological aqueous medium in vitro", "lactic acid and glycolic acid is of hydrophilic nature", and the release profile dependence/independence have not been given patentable weight, because they are inherent to the polylactide-glycolide excipients or the concentration of active agents.

Note, the intended use limited for a local pharmaceutical activity in the claimed composition has not been given patentable weight, because the prior art compositions would be at least capable of performing said use.

Please see MPEP § 2122 – Discussion of Utility in the Prior Art, which states, "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference." *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 74-90 and 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over HUCTHINSON (cited supra) in view of RAMCHANDANI et al (*In vitro and in vivo release of ciprofloxacin from PLGA 50:50 implants*. Journal of Control Release. 1998 Jul 31;54(2):167-75).

Applicant's claims are directed to a composition comprising of: at least 50% of an active agent, such as leuteinizing hormone-releasing hormone; and a biodegradable excipient, such as polylactide-glycolide, wherein the release profile of the active agent is continuous. The composition has a thin and elongated form with a diameter not

exceeding 3mm and the copolymers having an intrinsic viscosity greater than 0.6 dl/g. Further limitations include: a minimum length/diameter ratio of 10; and active agents at least 51% by weight.

As discussed above, HUTCHINSON disclosed a composition for implants (col. 16, line 24) comprised of: at least 50% of an active agent (col. 9, line 1-25), such as leuteinizing hormone-releasing hormone (col. 2, line 67); and a biodegradable excipient, such as polylactide-glycolide (col. 1, line 64), wherein the release profile of the active agent is continuous (abstract and col. 9, line 39). The composition has a thin and elongated form with a diameter not exceeding 3mm (col. 17, line 53-54) or in the form of spheres/pellets (col. 8, line 55-57); and the copolymers having an intrinsic viscosity greater than 0.6 dl/g (col. 9, line 1-25).

HUTCHINSON does not teach the limitations of: at least 51% of active agents; and a minimum length/diameter ratio of 10.

RAMCHANDANI teaches a microspheres (section 2.2) or implant (section 2.6) composition comprised of: an active agent, such as ciprofloxacin; and a biodegradable excipient, such as polylactide-glycolide (abstract), for localized therapy (abstract). Additionally, RAMCHANDANI disclosed the release of active agents from the implants was biphasic at ≤ 20% w/w drug loading, and monophasic at drug loading levels ≥ 35% w/w.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate drug loading levels ≥ 35% (which would include at least 51% of active agents) into HUTCHINSON's composition. The person of ordinary

skill in the art would have been motivated to make that modification and reasonably would have expected success, because it would allow more control of variables to create an implant with a continuous release of active agents at a higher dosage.

The references do not specifically teach producing a rod implant with a minimum length/diameter ratio of 10 as claimed by Applicant. The shape of a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jake M. Vu, PharmD, JD
Art Unit 1618

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER